

REMARKS

Claims 1-14 are presently in the subject application.

Claims 2, 4 and 5 have been amended to more particularly define and more adequately protect Applicants' invention.

Claims 8, 9, 11, 12 and 14 are rejected under 35 U.S.C. § 112, second paragraph, in the use of the term "anti-solvent". The Examiner forwards that "... the Examiner could find no mention of the term anywhere in the instant specification nor in the literature". In this regard, reference is made to the instant specification at page 16, the bridging paragraph, where it is stated,

Particles of the selected polysaccharide polymer system may be prepared using solutions or emulsion preparations... which may subsequently be dried by either the use of an **antisolvent** such as carbon dioxide, nitrogen or any other appropriate **antisolvent** ... (emphasis added)

The term "anti-solvent" or "antisolvent" is well known and understood in the art. For instance, reference is made to U.S. Patent No. 6,299,906 ("antisolvent phase"); U.S. Patent No. 6,517,840 ("... selective solvent are contacted with a nonsolvent or antisolvent ...") U.S. Patent No. 6,113,942 ("... to permit the precipitation of the desired substance ... upon addition of an antisolvent ..."); PSTT, Vol. 2, No. 11, November 1999, 430, at 433, ("Precipitation using SFs as non-solvents or antisolvents") and Pharmaceutical Research, Vol. 16, No. 7, 976, at 981 ("PRECIPITATION WITH ... ANTISOLVENTS"). Copies of these publications are enclosed herewith.

It is respectfully submitted that the term "anti-solvent" in claims 8, 9, 11, 12 and 14 does not render these claims indefinite, under 35 U.S.C. § 112, second paragraph, and allowance of these claims is respectfully requested.

Claims 8 and 9 are rejected under 35 U.S.C. § 112, second paragraph, in the use of the term "a critical pressure and temperature". The method as defined by claims 8 and 9 utilizes a standard technique to prepare Applicants' claimed construct, i.e., a conventional separation and drying technique utilizing a critical pressure and temperature and an antisolvent. This, again, is a well known processing technique within the art. One of ordinary skill in the art would know how to practice such technique. In this regard, reference is made to the publications identified above, and in particular, PSTT, *supra*, and Pharmaceutical Research, *supra*.

Additionally, reference is made to U.S. Patent No. 4,582,731 (a copy of which is enclosed), which has been incorporated into the instant specification by reference (page 17, line 3, "... supercritical fluid technology ..."; page 17, lines 4-5 and page 18, line 6).

It is submitted that claims 8 and 9 are not indefinite, under 35 U.S.C. § 112, second paragraph, and allowance of these claims is respectfully requested.

The Examiner has objected to claims 2, 4 and 5 for reciting non-elected inventions.

Claims 2, 4 and 5 have been amended whereby the medicament is the elected species, namely, insulin and the polymer is the elected alginic acid. Accordingly, claims 2, 4 and 5 are not subject to an objection and allowance thereof is requested.

Claims 1-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,475,468 ("PATENT"). Enclosed is a **Terminal Disclaimer** directed to the PATENT which overcomes the obviousness-type double patenting rejection. Accordingly, allowance of claims 1-14 is respectfully requested.


The Examiner is hereby authorized to call the undersigned attorney on record "collect" on any matter connected with this application. The telephone number is 212-588-0800. In the absence of the undersigned attorney or record, the call will be accepted by any attorney empowered in this application.

PATENT  
540541-2029

Enclosed herewith is a Request for a One Month Extension of Time with a check for  
\$110.00 to cover the fees.

Respectfully submitted,

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**VERSION WITH MARKINGS TO SHOW THE CHANGES MADE**

**IN THE CLAIMS**

Claim 2 has been amended as follows:

2 (Amended) The construct as defined in claim 1 wherein said polymer comprises [is selected from the group consisting of] alginic acid or a pharmaceutically acceptable salt thereof[; guar gum; gum karaya; gum Benjamin; plantago ovata gum; agar; carrageenan; cellulose; gum karaya; gum Benjamin, plantago ovata gum; agar; carrageenan; cellulose; gelatin; gum arabic, pectin, galacturonic acid and a mixture of any of the foregoing polymers].

Claim 4 has been amended as follows:

4. (Amended) The construct as defined in claim 3 wherein said medicament comprises [selected from the group consisting of an]insulin[, an insulin analog, an amylin, an immunodilating protein, an interleukin, an inteferon, an erythropoietan, a heparin, a thrombolytic, an antitrypsin, an anti-protease, a hormone, a growth factor, an enzyme, a nucleic acid, an immunoglobulin, an antibiotic, an antiinfective, a calcitonin, a hematopoietic factor, a vaccine, a vasoactive peptide, an antisense agent, an oligonucleotide, DNase, a cyclosporin, ribavirin or a mixture of any of the foregoing medicaments].

Claim 5 has been amended as follows:

5. (Amended) The construct as defined in claim 3 wherein said medicament comprises [is selected from the group consisting of an ]insulin[, an insulin analog, an amylin, glucagon, LH-RH, deltirex, leuprolide, gosorelin, nafarelin, octreotide, somatostatin, a calcitonin, porathyroid hormone, TRH, growth hormone-releasing hormone, G-CSF, G-SF, a cytokine, rhDNase, a heparin, an oligoneucleotide, ribavarin, glucagon, acetohexamide, chlorpropamide, tolazemide, tolbutamide, glipizide, glyburide, glucophage, phentolamine, tumor neurosis factor (TNF), nerve growth factor (NGF), macrophage-colony stimulating factor (M-CSF), heparinase,

bone morphogenic protein (BMP), hANP, glucagon-like peptide (GLP-1), renin, bradykinin, a bacitracin, a polymyxin, a colistin, tyrocidine, a gramicidin, a monoclonal antibody, a vaccine or a mixture of any of the foregoing medicaments].